InSight™ V-IA

Equid Serum Amyloid A（eSAA）Rapid Quantitative Test

INTENDED USE

The InSight V-IA Equine eSAA Rapid Quantitative Test is a fluorescence immunoassay used along with InSight V-IA Veterinary Immunoassay Analyser for quantitative determination of eSAA concentration in Equine serum, plasma or whole blood. The test is used to detect and monitor inflammation in Horses.

For *in vitro* diagnostic use only. For veterinary use only.

TEST PRINCIPLE

1.This test employs a quantitative double antibody sandwich fluorescence immunoassay technique.

2.The fluorescent signal intensity reflects the amount of eSAA captured and is processed in InSight V-IA Veterinary Immunoassay Analyser. The eSAA concentration is expressed in mg/L.

WARNINGS AND PRECAUTIONS

1.This kit is for in vitro diagnostic use only.

2.The Lot No. of all the test components (test device, ID chip and buffer) must match each other. Do not mix components from different kit lots.

3.Inspect the packaging and labels before use. Do not use if the pouch is broken, torn, unsealed or the cartridge/buffer is damaged.

4.Carefully follow the instructions and procedures described in this insert.

5.Do not use the test device beyond the expiration date. The test device must remain in its original sealed pouch until ready to use. Do not use if the pouch or the device itself is damaged, torn or unsealed.

6.A buffer tube should be used for processing one sample only.

7.One pipette tip should be used for one specimen only.

8.Do not touch the test area of the test device.

9.All samples and used test materials are considered potentially infectious. The used pipette tips, buffer tubes, test devices and samples must be handled carefully and disposed of in accordance with local regulations and procedures.

MATERIAL

Material Provided

- 10 individual sealed test cartridges
- One test device ID Chip
- Instructions for use
- 10 buffer tubes

Material Required but Not Provided

- InSight V-IA Veterinary Immunoassay Analyser
- Pipette
- Timer
- Centrifuge

STORAGE AND STABILITY

1.Store the test kit at 4～30℃ up to the expiration date.

2.Once the pouch has been opened, the test should be performed within an hour.

3.If removed from the refrigerator, allow 30 minutes for the test to attain room temperature before testing.

SPECIMEN COLLECTION AND PREPARATION

The test can be performed with either serum, Lithium Heparin plasma or whole blood.

For Whole Blood:

1.Following standard phlebotomy venipuncture procedure, collect whole blood sample containing anticoagulants.

2.It is recommended that samples should be tested immediately. Do not leave the samples at room temperature for prolonged periods. If the samples are not tested immediately, they should be stored at 2℃～8℃.

3.It is not recommended to test whole blood samples which have been stored at 2℃～8℃ for more than 48 hours.

For Plasma or Serum:

1.Following standard phlebotomy venipuncture procedure, collect whole blood sample using a blood collection tube.

If a plasma sample will be used, use blood collection tube containing a Lithium Heparin anticoagulant. If a serum sample will be used, use a plain serum tube.

2.Separate serum or plasma from blood within 2 hours after blood collection. If a sample appears to be severely haemolysed, another sample should be obtained and tested.

3.The test should be performed immediately after the sample collection. If the test cannot be performed within 2 hours after blood collection, store the sample at 2℃～8℃ for no longer than 48 hours. For long-term storage, samples should be kept below -20℃.

Bring all materials to room temperature before use. Frozen specimens must be completely thawed and mixed well prior to testing. Samples should not be frozen and thawed repeatedly. Only clear, non-haemolysed samples can be used.

TEST PROCEDURE

Refer to the InSight V-IA Veterinary Immunoassay Analyser User Manual for complete instructions for use of the analyser.

1.Set the test cartridge on a clean, level horizontal surface.

2.Make sure that the test cartridge Lot No. matches with the ID Chip No. Insert the ID Chip into the analyser. Be aware not to touch the insertion tip of the ID chip. Press ‘Read ID Card’ on the test screen.

3.Pipette 10µl of prepared sample into the buffer tube, gently mix well. Vigorous agitation and foaming should be avoided.

4.Pipette 75µl of mixed sample dilution to the sample well of the test cartridge. Avoid forming bubbles.

5.Please refer to Section V in the InSight V-IA Veterinary Immunoassay Analyser User Manual for details.

a) **Quick Test mode:** Set the timer for 5 minutes, start the timer immediately after adding the sample mixture to the sample well. Once the timer has counted down, insert the test cartridge immediately into the holder of the analyser and click ‘Test’. The instrument will scan the test device automatically and show the test result.

b) **Standard Test mode:** insert the test device into the device holder of the analyser immediately after adding the sample to the sample well, click ‘Test’. The analyser will start to countdown and read the test results automatically.

6.Results are displayed on the main screen and printed automatically.

INTERPRETATION OF RESULTS

The InSight V-IA Veterinary Immunoassay Analyser calculates eSAA test results automatically and displays the concentration of eSAA on the screen. For further information, refer to the User Manual of the InSight V-IA Veterinary Immunoassay Analyser.

Reference range of eSAA in equine blood:

1.Detection Range: 8~1500 mg/L

2. Reference Range: Normal: <20mg/L.

Each Laboratory should establish a reference range that is representative of the population to be evaluated.

QUALITY CONTROL

Each InSight V-IA eSAA Rapid Quantitative Test contains an internal control for routine quality control requirements. This internal quality control is performed each time a patient sample is tested. If an invalid result from the internal control occurs, the analyser will display an error message, indicating that another test should be performed.

LIMITATIONS OF PROCEDURE

1.This test is developed for testing Equine serum, plasma or whole blood.

2.The results of InSight V-IA eSAA Rapid Quantitative Test should be evaluated with all clinical and laboratory data available. If test results do not agree with the clinical evaluation, additional tests should be performed accordingly.

3. The performance of the test is highly sensitive to the storage and handling conditions of kits and samples.

4.There is the possibility that factors such as technical or procedural errors may interfere with the test and cause erroneous results.

5. EDTA will interfere in lower test results and cause false elevation of results.

MANUFACTURED BY

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